

REMARKS

Claims 1-5, 7-9, 11-13, and 37-43 are pending in the application. The Office Action states that claims 38-43 have been withdrawn from consideration, although as discussed below, it is believed that claim 38 has been examined and considered and should remain in the application.

Applicants respectfully request reconsideration and reexamination of this application.

Elections/Restrictions

The Examiner has withdrawn claims 38-43 as being drawn to a non-elected species. Applicants respectfully note that the election of species requirement in the Office Action of April 17, 2008, required election of one of the following species:

- i. electrochemically deposited coating;
- ii. electrophoretically deposited coating;
- iii. sol gel deposited coating;
- iv. aerosol deposited coating;
- v. dip-coated deposited coating; and
- vi. spin-coated deposited coating.

In a Response filed May 6, 2008, Applicants elected species to an electrochemically deposited coating and submitted that claim 38 specifically reads on this species. Moreover, Applicants note that "claim 37" is rejected over Gao et al. in view of Kotte et al., which is cited by the Examiner describing an electrochemically deposited coating. Because claim 37 does not contain a limitation to an electrochemically deposited coating, it appears that the Examiner actually examined claim 38 and intended that claim 38 remain in the application.

Accordingly, Applicants respectfully submit that the withdrawal of claim 38 from this rejection is in error and will treat claim 38 as being considered in this Response.

Rejection Under 35 U.S.C. § 102(b)

Claims 1, 2, 8, 9, and 13 are rejected under 35 U.S.C. § 102(b) as being by U.S. Patent No. 6,113,993 ("Gao et al."). The Examiner asserts that Gao et al. discloses "an implant comprising a substrate and calcium phosphate coating on the substrate wherein the coating has a thickness of less than 1 μm ". While the Examiner implies that Gao et al. does not disclose a

stent, the Examiner asserts that the claim language "does not provide any structural limitations limiting the system to a stent." Applicants respectfully traverse this rejection.

Applicants respectfully disagree that the claim should not be limited to a stent because it does not recite structural features of a stent. Applicants respectfully submit that the term "stent" in itself denotes structural features that are well known in the medical device field. The specification provides a standard definition of a stent, which is a metallic mesh tube that is inserted into a blood vessel in contracted (crimped) form (second paragraph of specification). When situated at the appropriate location in the vessel, the stent is expanded radially via a balloon (*Id.*) The stent remains in the vessel in its expanded form, serving as a support scaffolding for blood vessel walls (*Id.*) As a result, the vessel aperture is increased as well as the blood flow (*Id.*)

This definition is consistent with other references cited by the Examiner, namely U.S. Publication No. 2001/0029351 ("Falotico et al.") and U.S. Patent No. 6,663,664 ("Pacetti"). Falotico et al. describes a stent as having a substantially tubular body (§[0018]) that is inserted into a body lumen in a non-expanded form and then expanded either autonomously or with the aid of a second device, e.g., a catheter-mounted balloon (*Falotico* at §[0035]). The stent is expanded circumferentially and maintained in an expanded configuration (*Id.*) A similar definition is provided in Pacetti, which describes a stent as a generally cylindrically shaped device delivered in a compressed condition to a target site (blood vessel or other arterial lumen) (*Pacetti* at col. 1, ll. 16-20). At the target site, the stent is deployed into an expanded condition to support the vessel and maintain it in an open position (*Id.* at col. 1, ll. 20-22).

Thus, the specification, and the art cited provide a consistent definition of a stent reciting the structural features of a tubular or cylindrical mesh having dimensions that allow it to be delivered into a body lumen in compressed form, upon which it is expanded radially (circumferentially) to support the vessel thereby increasing its aperture. Because the term "stent" in itself conveys structural features well known in the art, it is submitted that no other structural recitations are necessary.

Applicants respectfully submit that the structural features of a "stent" are found nowhere in the devices of Gao et al. Gao et al. describes medical devices such as prosthetic implants for bone or dental implants, which are well known in the art as being nondeformable. Indeed, it is desired that these devices be nondeformable as implants for bone and teeth are necessarily rigid. Moreover, the devices of Gao et al. do not have a tubular shape specifically dimensioned to be inserted into a lumen, and when subsequently radially expanded, capable of supporting the lumen without rupture or damage to the lumen walls. Accordingly, Gao et al. fails to disclose a stent.

Because Gao et al. fails to disclose a stent, Gao et al. does not anticipate the present claims. Accordingly, Applicant respectfully requests withdrawal of this rejection.

Rejections under 35 U.S.C. § 103(a)

Gao et al.

Claims 3, 4, and 7 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Gao et al. The Examiner asserts that Gao et al. addresses all the limitations of claim 1. Applicants respectfully traverse this rejection.

As discussed above, Gao et al. fails to teach the use of a stent or any device: (1) capable of deformation, and (2) dimensioned for initial insertion in a blood vessel and after expansion can support the vessel walls without damage to the walls. Moreover, there is no rationale in Gao et al. that would lead one skilled in the art to coat a substrate of a stent with a calcium phosphate for at least the reasons outlined below.

(1) Orthopedic and dental implants were coated with calcium phosphate for their osseointegrative properties.

Gao et al. describes prosthetic implants for bone as being made of a titanium alloy due to its corrosion resistance in body fluids (*Gao et al.* at col. 1, ll. 18-20). The alloy itself is not bonded to bone but rather coated with a calcium phosphates to enhance bone apposition to endosseous implants (*Id.* at col. 1, ll. 20-23). The calcium phosphate allows the bone to bond to the coated prosthetic surface and enhance fixation of the implant (*Id.* at col. 1, ll. 23-25). Gao et al. lists hydroxyapatite and tricalcium phosphate as "particularly attractive materials for

coating titanium for hard tissue implants" as they allow direct integration to bone tissues by resorption or by facilitating bone bonding via newly formed bone (*Id.* at col. 1, ll. 25-32). Thus, Gao et al. provides a rationale for, and as well known in the art, touts calcium phosphates as a desired coating choice for those devices that can osseointegrate with hard tissues, such as bone or teeth.

In contrast, since osseointegration is inapplicable to stent technology, there is no rationale for coating a stent with a calcium phosphate. A stent is placed in a body lumen, which does not contain hard tissue such as bone or teeth. There would be no reason for a calcium phosphate coating on a stent as osseointegration is not necessary. One skilled in the art would not coat a stent with a calcium phosphate simply because such coatings existed in orthopedic or dental implants.

(2) It would not be obvious to coat a deformable device with a hard ceramic such as calcium phosphate.

Calcium phosphates are known in the art as ceramics. It is also well known that ceramics are hard, rigid materials that crack or break when deformed. Gao et al. finds the use of hydroxyapatite and tricalcium phosphate as "particularly attractive materials for coating titanium for hard tissue implants" (*Gao et al.* at col. 1, ll. 11-13 and 25-27). Calcium phosphates would be ideally suited for coating orthopedic or dental implants as these prosthetics are, like ceramics, nondeformable and hard.

In contrast, as discussed above, a stent is a device that undergoes radial expansion upon installation at site. It would be assumed that a device that experiences deformation, such as a stent, would not ideally be coated with a hard, brittle material such as a ceramic. As evidence of this thinking in the art, commercially available coated stents, such as the Cypher® stent (Johnson & Johnson/Cordis Corp.) the Taxus® stent (Boston Scientific) are coated with a polymer, which is a material that is well known to be capable of deformation. Thus, one skilled in the art would reason that a deformable device would ideally have a deformable coating and not a hard coating such as a calcium phosphate.

(3) One skilled in the art of stent manufacture would not subject a stent to the PEMOCVD conditions of Gao et al.

Gao et al.'s method of coating an orthopedic or dental implant is derived from a "technically unrelated field of semiconductor manufacture" and involves applying a plasma-enhanced metalorganic chemical vapor deposition (PEMOCVD) for coating the implants (*Id.* at col. 1, ll. 44-49). Gao et al. further discloses that materials such as calcium phosphate and hydroxyapatite were not previously deposited as coating materials via PEMOCVD (*Id.* at col. 1, ll. 48-49 and col. 2, ll. 18-24). The PEMOCVD method involves a gaseous stream of coating precursors and an oxygen plasma directed toward a heated substrate (*Id.* at col. 2, ll. 63-66). The substrate is heated to a minimum temperature sufficient to decompose the precursors, where the minimum temperature for calcium phosphate is about 200°C (*Id.* at col. 3, ll. 31-38). In specific examples, Gao et al. discloses deposition temperatures as high as 500 to 650°C (*Id.* at col. 4, ll. 35-36). A reaction takes place to form the calcium phosphate coating where reaction byproducts are pumped out (*Id.* at col. 3, ll. 1-2). Gao et al. describes the coating as dense (*Id.* at col. 3, ll. 56-58).

It would not be obvious to coat a stent with a calcium phosphate based on Gao et al., as one skilled in the art of coating stents would not subject a stent to the extreme conditions of PEMOCVD, including:

- high temperatures, as high as 500 to 650°C
- an oxygen plasma at high temperatures
- a reaction in which reaction byproducts must be pumped out.

Applicants submit herewith a paper by Poncin et al. as evidence that one skilled in the art would not have applied Gao et al.'s PEMOCVD method to a stent (Poncin et al., "Stent Tubing: Understanding the Desired Attributes," Materials & Processes for Medical Devices Conference, ASM International, 8-10 September 2003). Although Poncin et al. was published after the earliest filing date of the present application, it is submitted that Poncin et al. is relevant for showing the general knowledge of one skilled in the field of stents.

Poncin et al. describes the material properties and physical attributes necessary for a metal tubing to function as a stent. A stent must balance the properties of low yield strength to allow strength expansion (Poncin et al. at p. 1, col. 2). High tensile properties are desired for high

radial strength after expansion while preventing recoil after expansion (*Id.*). Moreover, the stent material must possess minimal impurities (*Id.*). Table 1 of Poncin et al. shows the desired physical and mechanical properties of stents made from various materials, including density, elastic modulus, ultimate tensile strength, yield strength, UTS-yield, elongation percent, and elastic range.

Poncin et al. also describes "important desirable tubing attributes," including the nature and purity of the elemental material components mixed prior to melting, homogeneity, porosity, and microcleanliness of the alloy (*Id.* at p. 5, col. 2). Despite ASTM and ISO standards, Poncin et al. states that these standards "are often not sufficient to bring the required safety in a stent application" (*Id.*). As an example, defects of 15 μm thick can be massive with respect to stent struts having dimensions thinner than 100 μm , and can result in rupture upon expansion or fatigue failure.

It can be readily seen that the severe reaction conditions of Gao et al. are not applicable to stents because such conditions could lead to excessive oxidation or a change in the properties of the metal or metal alloy due to the high temperature/oxygen plasma conditions. Also, such oxidation or impurities arising from reaction by-products between PEMOCVD precursors could result in damage to the metal surface of stents or defects that would affect the metal purity.

Moreover, it would not be obvious to coat a stent with a rigid ceramic material, where a stent requires well defined properties such as yield strength, tensile properties, elastic modulus, and other properties, as outlined by Poncin et al.

Applicants respectfully submit that Gao et al. fails to render obvious a stent coated with a calcium phosphate, and respectfully request withdrawal of this rejection.

Gao et al. and Zhang et al.

Claims 5 and 37 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Gao et al. in view of U.S. Patent No. 7,157,096 ("Zhang et al."). The Examiner admits that Gao et al. fails to disclose a tensile bond strength value between the substrate and calcium phosphate, and turns to Zhang et al. for purportedly teaching implants having multiple layers comprising a

bond strength greater than or equal to 60 MPa. The Examiner further alleges that it would be obvious to modify the bond strength to provide a layer that sufficiently bonds the substrate. Applicants respectfully traverse this rejection.

As discussed above, Gao et al. fails to render obvious a stent coated with a calcium phosphate. Zhang et al. fails to remedy this deficiency. Like Gao et al., Zhang et al. fails to disclose coating a stent or deformable substrate. Zhang et al. instead describes coating implants such as orthopedic or dental implants (*Zhang et al. at abstract*). Zhang et al. explains that calcium phosphates such as hydroxyapatite have a similar composition to principal components of hard tissues such as bone (*Id. at col. 1, ll. 25-29*). Zhang et al. describes the "excellent osteoconductivity" of apatites, leading to their widespread use as a coating on implants and prostheses, and mentions "increased bone or other favorable tissue growth onto the surface of the apatite coated metal implant" (*Id. at col. 1, ll. 29-40*). Like Gao et al., Zhang et al. aims to coat nondeformable prostheses widely known for being coated with calcium phosphates, and which prosthesis would directly benefit from the osteoconductivity and integration of the coating. Zhang et al. fails to lead one skilled in the art to coat a stent that would be implanted in a blood vessel and would have no contact with a calcium phosphate component.

Moreover, Zhang et al. describes the tendency of apatites to delaminate and crack due to a large thermal expansion coefficient difference between the apatite and metallic substrate, such as a difference of $3.3 \times 10^{-6}/^{\circ}\text{C}$ between hydroxyapatite and a metallic alloy such as Ti6Al4V (*Id. at col. 1, ll. 55-60*). While Zhang et al. accounts for differences of thermal expansion coefficients between apatites and rigid metallic substrates, this difference of expansion coefficients does not begin to approach the difference in expansion properties of a ceramic versus that of a deformable stent. Thus, Zhang et al. confirms what is well known in the art, namely that it would not be obvious to coat a deformable device such as a stent with a rigid material like a calcium phosphate that has a tendency to delaminate and crack.

Applicants respectfully submit that neither Gao et al. nor Zhang et al., taken alone or together, render obvious the claimed invention and respectfully request withdrawal of this rejection.

Gao et al., Zhang et al., and Falotico et al.

Claim 11 is rejected under 35 U.S.C. § 103 as being unpatentable over Gao et al. in view of Zhang et al. and further in view of U.S. Pub. No. 2001/0029351 ("Falotico et al."). The Examiner admits that Gao et al. fails to disclose a substrate having two calcium phosphate coatings where a drug is contained in both coatings. Zhang et al. fails to disclose a drug in a first coating. The Examiner turns to Falotico et al. for allegedly disclosing a stent having the claimed coatings.

Applicants respectfully submit that neither Gao et al. nor Zhang et al. render obvious a stent having a calcium phosphate coating. Falotico et al. fails to remedy this deficiency. While Falotico et al. is directed to stents, there is no teaching in Falotico et al. to guide one skilled in the art to coat a stent with a calcium phosphate. Falotico et al. merely describes what is well known in the stent field, namely in that stents are balloon-expandable slotted metal tubes expanded within the lumen of an artery to provide rigid scaffolding to the arterial wall (*Falotico et al.* at p. 2, [0014]).

Falotico et al. describes various embodiments of a stent capable of containing and releasing drugs, agents, or compounds. In one embodiment, for example, reservoirs 106 can be provided within bands 102 of stent 100 to hold the drug or agent (*Id.* at p. 4, ¶ [0040] and FIG. 1). Alternatively, a drug such as rapamycin can be incorporated into a polymeric matrix and sprayed onto the stent (*Id.* at p. 5, ¶ [0046]). Falotico et al. describes standard methods for coating a stent, i.e., either the use of discrete pockets or reservoirs within the metal stent itself, or a polymer coating, which is a deformable material that can withstand the deformation of a stent. There is no mention in Falotico et al. of the use of a rigid material such as a ceramic, e.g., a calcium phosphate, for coating a stent. Based on the state of the art as represented by Falotico et al., one skilled in the art would have believed that a calcium phosphate would be too rigid and/or brittle for coating a deformable structure such as a stent.

Applicants respectfully submit that the combination of Gao et al., Zhang et al. and Falotico et al. do not render obvious the claimed invention and respectfully request withdrawal of this rejection.

Gao et al., Falotico et al. and Pacetti

Claim 12 is rejected under 35 U.S.C. § 103 as being unpatentable over Gao et al. in view of Falotico et al. Although Pacetti is not mentioned in the formal rejection, the Examiner discusses Pacetti in this section. Accordingly, Applicants assume the rejection is based on Gao et al. in view of Pacetti and further in view of Falotico et al.

The Examiner admits that Gao et al. fails to disclose a drug that inhibits restenosis and turns to Pacetti for disclosing a stent for preventing restenosis and comprising a therapeutic drug, and to Falotico et al. for describing a drug that inhibits restenosis. Applicants respectfully traverse this rejection.

As discussed above, Gao et al. does not render obvious a stent, or any deformable medical device, coated with a calcium phosphate. Falotico et al. describes standard methods for coating a stent with a drug, such as a reservoir in the stent itself or via a polymer coating, which is known to be deformable. Pacetti does not remedy this deficiency. Pacetti fails to disclose a calcium phosphate coating having the claimed thickness, as described in greater detail below.

Applicants respectfully submit that the combination of Gao et al., Falotico et al. and Pacetti do not render obvious the claimed invention and respectfully request withdrawal of this rejection.

Gao et al. and Kotte et al.

Claim 37 is rejected under 35 U.S.C. § 103 as being unpatentable over Gao et al. and further in view of Kotte et al. Applicants assume this rejection is directed toward claim 38, and not claim 37, because claim 38 recites an electrochemically-deposited coating.

The Examiner admits that Gao et al. fails to disclose an electrochemically deposited coating and turns to Kotte et al. for this teaching. Applicants respectfully traverse this rejection.

Kotte et al. is directed to a coated device for bone implants, dental implants, artificial joints, and fixative material for accident surgery, i.e., osteosynthesis material (*Kotte et al.* at p. 1, ¶ [0001]. According to Kotte et al., coated implants "integrate better with calcium phosphate, in particular with the bone mineral hydroxyapatite" (*Id.* at p. 1, ¶ [0002]).

As with Gao et al., Kotte et al. is directed towards devices that are capable of osseointegration with components in the body having a calcium phosphate component, such as bone and teeth. There is no reasoning in either Gao et al. or Kotte et al. for coating a stent, which is positioned within a blood vessel that has no bone or dental material, to take advantage of the osseointegrative properties of calcium phosphates.

Moreover, the electrochemical deposition of Kotte et al. would not provide a calcium phosphate coating of less than 1 μm . Kotte et al. describes an apatite-coated metallic material having a "thick covering of hydroxyapatite crystals" (*Id.* at p. 1, ¶ [0010]). Preferably, the crystals of Kotte et al. have a needle length of 200-300 nm and/or spheres having a diameter in the range of 35 to 200 nm with a total coating layer thickness of $> 1 \mu\text{m}$, and preferably from 2 to 5 μm (*Id.*). Finally, there is no indication that the calcium phosphate coating of Kotte et al. would be useful for coating a deformable structure such as a stent. Instead, Kotte et al. teaches the provision of a "thick" coating, which would interfere with the stent crimping and expansion properties. It is submitted that Kotte et al. actually teaches directly away from the claimed range of less than 1 μm .

Applicants respectfully submit that Gao et al. and Kotte et al. do not render obvious the claimed invention and respectfully request withdrawal of this rejection.

Pacetti in view of Gao et al.

Claims 1, 3, 4, 7-9, and 13 are rejected under 35 U.S.C. § 103 as being unpatentable over Pacetti in view of Gao et al.. The Examiner asserts that Pacetti discloses a stent for preventing restenosis having a coating of tricalcium phosphate. The Examiner admits that Pacetti does not disclose a coating thickness and turns to Gao et al. for teaching an implant with a coating thickness of less than 1 μm . Applicants respectfully traverse this rejection.

Pacetti discloses a self-expanding stent having flexible segments that allow the stent to bend and deform from a collapsed position to an expanded position (*Pacetti* at abstract). Pacetti adds biodegradable material associated with the flexible segments to change the bending characteristics of the segments and alter the amount of contraction and expansion exhibited by the stent (*Id.*). While non-self-expanding stents are deformed with a balloon catheter, self-expanding stents must achieve a high initial radial force to either hold open or open a

previously tight stenosis without the use of a balloon (*Id.* at col. 2, ll. 50-53). According to Pacetti, this force can be achieved in a self-expanding stent by oversizing the stent or by providing thicker and wider struts (*Id.* at col. 2, ll. 57-60).

More specifically, the flexible segments in the stent of Pacetti has the necessary outward radial force to cause this expansion (*Id.* at col. 3, ll. 53-61). The biodegradable material is placed within the strut junction to act as a bend control member and thereby influence the amount of radial force to be exerted (*Id.* at col. 3, ll. 61-65). When the stent is crimped to its collapsed position, the strut junctions are under greater stress with the biodegradable material in place than without the material (*Id.* at col. 4, ll. 4-7). FIG. 1 shows biodegradable control members 25 positioned to selectively control the bending of the flexible segments (*Id.* at col. 6, ll. 66-67). A list of biodegradable materials is included at col. 9, l. 64, to col. 10, l. 11.

Applicants respectfully submit that one skilled in the art would not incorporate a calcium phosphate as the biodegradable member of Pacetti where the calcium phosphate has a thickness of less than 1 μm . Pacetti requires that the biodegradable member control the radial force of a stent and withstand the stress of maintaining the stent in a collapsed position prior to expansion. If one were to choose calcium phosphate as the biodegradable member, they would not have selected a thickness of less than 1 μm to control radial expansion forces. It would be readily apparent that for stent struts approximating dimensions of 100 μm (see Poncin, above), the biodegradable member would require a dimension greater 1 μm in order to withstand the forces described by Pacetti, particularly where the biodegradable member is a brittle material such as a calcium phosphate.

One skilled in the art would incorporate a coating thickness depending on the type of device; such thicknesses are not readily interchangeable as implied by this rejection. It would not be logical or obvious to use Gao et al.'s thickness of less than 1 μm in the biodegradable member of Pacetti. For example, the method of Gao et al. is directed to coatings for devices that are not placed under stress, i.e., the coatings of Gao et al. are applied to nondeformable devices. In contrast, the device of Pacetti is deformable and the biodegradable member has a function to withstand and control high radial forces and stresses. The coating thickness of Gao et al. would be inapplicable to the device of Pacetti. Thus, the combination of Pacetti and Gao et al. is improper.

Accordingly, Applicants respectfully submit that the combination of Pacetti and Gao et al. does not render obvious the claimed invention and respectfully request withdrawal of this rejection.

Pacetti, Gao et al., Zhang et al. and Falotico

Claim 11 is rejected under 35 U.S.C. § 103 as being unpatentable over Pacetti in view of Gao et al. and further in view of Zhang et al. and further in view of Falotico et al. The Examiner asserts that Pacetti addresses all of the limitations of claims 1 and 9. However, Applicants respectfully note that if this were the case, the Examiner would have applied Pacetti as a novelty-defeating rejection. Instead, the Examiner used Gao et al. for disclosing the claimed thickness. Moreover, Zhang et al. is cited for disclosing an implant having two calcium phosphate coatings and Falotico et al. is cited for disclosing a stent having two coatings where a drug is present in each coating. Applicants respectfully traverse this rejection.

As Applicants have discussed throughout this Response, one skilled in the art would have designed a coating material and its respective dimensions depending on the type of device and its function. The Examiner's rejection randomly applies coating materials and dimensions without regard to the type of device. Pacetti and Falotico et al. describe deformable devices, i.e., a stent, that undergoes radial expansion and thus, are subjected to radial forces and stresses. Gao et al. and Zhang et al., in contrast, are directed to rigid orthopedic or dental implants that require calcium phosphate for osseointegration. There would be no rationale for coating a stent with a calcium phosphate as there are no components within a blood vessel that requires fixation to a device via osseointegration.

Furthermore, orthopedic and dental implants are rigid and nondeformable devices that could incorporate rigid ceramics as a coating, such as calcium phosphate. However, the rejection applies such coatings to the deformable stents of Pacetti and Falotico et al. This is not the case, though. Pacetti requires a biodegradable member to control flexible segments that experience high radial forces. There is no specific description of a calcium phosphate coating. Moreover, Pacetti would not use a calcium phosphate having an extremely small dimension, i.e. Gao et al.'s thicknesses of less than 1 μm to contain and control the radial forces. In contrast Gao et al. applies thin coatings to nondeformable devices that do not experience these stresses.

Falotico et al., in contrast to the other references, describes the use of in-stent reservoirs or polymer coatings that are capable of deforming with the stent.

Applicants respectfully submit that the combination of Pacetti, Gao, Zhang, and Falotico does not render obvious the claimed invention and respectfully request withdrawal of this rejection.

Pacetti, Gao et al. and Falotico et al.

Claim 12 is rejected under 35 U.S.C. § 103 as being unpatentable over Pacetti in view of Gao et al. and further in view of Falotico et al. The Examiner alleges that the modified Pacetti (with the teachings of Gao et al.) addresses all the limitations of claims 1 and 9 and turns to Falotico et al. for disclosing a drug that inhibits restenosis. Applicants respectfully traverse this rejection.

As outlined above, it would not be obvious to incorporate a biodegradable member in the stent of Pacetti with the dimensions of Gao et al. Pacetti describes incorporating a biodegradable member to control radial expansion of flexible segments of a stent and would not use the small thicknesses of Gao et al. Falotico et al. does not remedy this deficiency. Falotico et al. is directed to a polymeric coating, which is known to be deformable and thus capable of coating a deformable device. As Falotico et al.'s teachings are not applicable to a calcium phosphate coating, which was known to be nondeformable, the combination with Falotico et al. is improper.

Accordingly, Applicants respectfully submit that the combination of Pacetti, Gao et al. and Falotico et al. does not render obvious the claimed invention and respectfully request withdrawal of this rejection.

Conclusion

Applicants respectfully submit that the combination of references cited in this Office Action do not take into account the important differences between the types of devices, the uses of the devices, the strategies for selecting a particular material, and the applicable thicknesses of the devices, as disclosed in the references and as disclosed and claimed in the subject application. Instead, the selection of references is clearly the result of hindsight, and one skilled in the art would not apply the teachings of the references in the manner outlined in the Office Action.

[A] patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. Although common sense directs one to look with care at a patent application that claims as innovation the combination of two known devices according to their established functions, it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.

KSR Int'l Co. v. Teleflex Inc., 127 S.Ct. 1727, 1741 (2007). Applicants respectfully submit that no such reasoning has been identified for combining the references as outlined in this Office Action, and respectfully request withdrawal of these rejections.

Reconsideration

It is believed that all claims of the present application are now in condition for allowance.

Reconsideration of this application is respectfully requested. If the Examiner believes that a teleconference would expedite prosecution of the present application the Examiner is invited to call the Applicant's undersigned attorney at the Examiner's earliest convenience.

Any amendments or cancellation or submissions with respect to the claims herein is made without prejudice and is not an admission that said canceled or amended or otherwise affected subject matter is not patentable. Applicant reserves the right to pursue canceled or amended subject matter in one or more continuation, divisional or continuation-in-part applications.

Please grant any extensions of time required to enter this response and charge any fees in addition to fees submitted herewith that may be required to enter/allow this response and any accompanying papers to our deposit account 02-1037 and credit any overpayments thereto.

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